

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/827,432	IZMAILOV ET AL.	
	Examiner Cheyne D. Ly	Art Unit 2168	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTO-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1.  This communication is responsive to interview on December 13, 2007.
2.  The allowed claim(s) is/are 14-19 and 21-27.
3.  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a)  All b)  Some\* c)  None of the:
    1.  Certified copies of the priority documents have been received.
    2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3.  Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4.  A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5.  CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a)  including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1)  hereto or 2)  to Paper No./Mail Date \_\_\_\_\_.
  - (b)  including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6.  DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

#### Attachment(s)

1.  Notice of References Cited (PTO-892)
2.  Notice of Draftsperson's Patent Drawing Review (PTO-948)
3.  Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4.  Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5.  Notice of Informal Patent Application
6.  Interview Summary (PTO-413),  
Paper No./Mail Date December 13, 2007
7.  Examiner's Amendment/Comment
8.  Examiner's Statement of Reasons for Allowance
9.  Other \_\_\_\_\_.

### **EXAMINER'S AMENDMENT**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.
2. Authorization for this examiner's amendment was given in a telephone interview with Chris Wight on December 13, 2007.
3. Cancel claims 20 ad 28-30.

### **IN THE CLAIMS**

**REPLACE** Claim 14 with claims 14 amended by examiner (without underlined and cross marked) set forth below:

14. A method for alignment of a plurality of data traces indicative of the positions of a plurality of nucleic acid base types in a target nucleic acid sequence, comprising the steps of:
- (a) selecting for each data trace one or more alignment points corresponding to an internal peak associated with internal bases that are highly conserved in the target nucleic acid, wherein said highly conserved internal bases are of expected type in at least 98 percent of actual samples, and further selecting alignment points selected from the group consisting of a primer peak associated with unextended primer, a full-length peak associated with full length product produced during a cyclic primer extension reaction with two

primers, and assigning to each selected alignment point a reference position number reflecting the relative position of the alignment point with respect to the sequence as a whole;

- (b) assigning a sequence position number to each peak in each of the plurality of data traces that maximizes the number of times that the sequence position number and the reference position number are assigned to a base of the same type;
- (c) aligning the data traces based on the assigned sequence position numbers;
- (d) determining the sequence of the nucleic acid bases according to the aligned data traces; and
- (e) displaying the determined sequence of nucleic acid bases.

**REPLACE** Claim 18 with claims 18 amended by examiner (without underlined and cross marked) set forth below:

18. (Previously Presented) A method for alignment of a plurality of data traces indicative of the positions of a plurality of nucleic acid base types in a target nucleic acid sequence, comprising the steps of:
- (a) selecting for each data trace a set of three or more alignment points, wherein at least one alignment point corresponds to an internal peak

associated with internal bases that are highly conserved in the target nucleic acid, wherein said highly conserved internal bases are of expected type in at least 98 percent of actual samples, and further selecting alignment points selected from the group consisting of a primer peak associated with unextended primer, a full-length peak associated with full length product produced during a cyclic primer extension reaction with two primers, and assigning to each selected alignment point a reference position number reflecting the relative position of the alignment point with respect to the sequence as a whole;

(b) determining the average peak spacing interval between each of the alignment points in each of the plurality of data traces and assigning sequence position numbers to peaks occurring at each interval that maximizes the number of times that the sequence position number and the reference position number are assigned to a base of the same type, wherein the sequence position numbers are used for aligning the data traces based on the assigned sequence position numbers;

(c) aligning the data traces based on the assigned sequence position numbers;

(d) determining the sequence of the nucleic acid bases according to the aligned data traces; and

(e) displaying the determined sequence of nucleic acid bases.

**REPLACE** Claim 19 with claims 19 amended by examiner (without underlined and cross marked) set forth below:

19. (Previously Presented) A method for alignment of a plurality of data traces indicative of the positions of a plurality of nucleic acid base types in a target nucleic acid sequence, comprising the steps of:

(a) selecting for each data trace a set of five or more alignment points, wherein at least one alignment point corresponds to an internal peak associated with internal bases that are highly conserved in the target nucleic acid, wherein said highly conserved internal bases are of expected type in at least 98 percent of actual samples, and further selecting alignment points selected from the group consisting of a primer peak associated with unextended primer, a full-length peak associated with full length product produced during a cyclic primer extension reaction with two primers, and assigning to each selected alignment point a reference position number reflecting the relative position of the alignment point with respect to the sequence as a whole;

(b) determining the average peak spacing interval between each of the alignment points in each of the plurality of data traces and assigning sequence position numbers to peaks occurring at each interval that

maximizes the number of times that the sequence position number and the reference position number are assigned to a base of the same type, wherein the sequence position numbers are used for aligning the data traces based on the assigned sequence position numbers;

- (c) aligning the data traces based on the assigned sequence position numbers;
- (d) determining the sequence of the nucleic acid bases according to the aligned data traces; and
- (e) displaying the determined sequence of nucleic acid bases.

4. The prior art of record fails to teach or suggest the claimed invention individually or in combination the limitation of " **said highly conserved internal bases are of expected type in at least 98 percent of actual samples**" as set forth in claims 14, 18, and 19.

5. Dependent claims 15-17 and 21-27 being further limiting to the independent claim 14, 18, or 19, are definite, and enabled by the specification (page 6, lines 7-8), as directed to the limitation of **said highly conserved internal bases are of expected type in at least 98 percent of actual samples**, are also allowed.

6. The closest prior art, Yeager et al., describes high performance DNA sequencing, and the detection of mutations and polymorphisms, on the Clipper sequencer. Further, Gilchrist et al. describes a method and apparatus for alignment of signals for use in DNA base-calling.

However, the references, alone or in combination, do not teach or suggest the limitations cited above as being free of any prior art when read in the claims as a whole.

## **CONCLUSION**

7. Claims 14-19, and 21-27 are allowed.
8. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.
9. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199. The USPTO's official fax number is 571-272-8300.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

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11. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tim Vo, can be reached on (571) 272-3642.

/Cheyne D Ly/  
C. Dune Ly  
Primary Examiner  
21/01/2008